

EXHIBIT A

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3

4 In re:)
5 PHARMACEUTICAL INDUSTRY) CA No. 01-12257-PBS
6 AVERAGE WHOLESALE PRICE) MDL No. 1456
7 LITIGATION)

8 MOTION HEARING
9 BEFORE THE HONORABLE PATTI B. SARIS
10 UNITED STATES DISTRICT JUDGE
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14 United States District Court
15 1 Courthouse Way, Courtroom 19
16 Boston, Massachusetts
17 May 23, 2006, 3:05 p.m.
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23 LEE A. MARZILLI
24 CERTIFIED REALTIME REPORTER
25 United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
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1 from that use of AWP.

2 So that's what AWP is. It's a reporting system,
3 and there's a lot of behavior that is organized around that
4 system. It's not a system that was created by the
5 pharmaceutical industry. Quite to the contrary, it was
6 created, it seems, by some interactions between payors and
7 government agencies. That seems to be a little bit lost in
8 the midst of time, I'm not sure it's terribly relevant, but
9 it's a system that has a lot of participants; and actually
10 one of the least active participants are the pharmaceutical
11 manufacturers, though for sure we set that AWP. And AWP has
12 a known, predictable, and disclosed relationship in the
13 branded industry to WAC, the wholesale acquisition cost.

14 On the generic side of the market, AWP has a known
15 predictable relationship, within a modest range, to the
16 branded AWP at the time that the generic versions of that
17 product are launched into the marketplace.

18 THE COURT: You know, Mr. Montgomery, as you know,
19 we've both read the same expert reports. I have a sense of
20 all of this.

21 MR. MONTGOMERY: Right.

22 THE COURT: So let's just jump to the fact it was
23 put into a statute.

24 MR. MONTGOMERY: Yes. Well, it was first put into
25 a regulation in 1991 by HCFA. And so your question, I'm

1 sure, is, well, what did HCFA mean? And what HCFA meant, we
2 submit -- and we think the record is perfectly clear and
3 robust on this -- is that HCFA was adopting that system, that
4 commercial system that existed in the marketplace, to utilize
5 it in order to determine, for one particular federal program,
6 how the pricing system would work.

7 The very agency that made that decision in 1991 had
8 for twenty years or so had experience with AWP, understood
9 exactly what AWP was, and decided to adopt it in 1991 and
10 1992, after having decided two years earlier that it was not
11 appropriate to adopt a national Medicare fee structure for
12 pharmaceuticals. They didn't want to do that.

13 Now, the very next year in 1990, they developed a
14 very elaborate program for the Medicaid prescription drug
15 program in the form of the AMP and best price provisions. So
16 the government knew exactly how to go about creating a very
17 precise disclosure mechanism that would disclose exactly what
18 the least average acquisition prices might be. They knew how
19 to do that. But for a number of reasons with respect to the
20 Medicare program, the record in front of you -- and I know
21 we're all looking at the same record -- shows that they
22 decided not to do it.

23 THE COURT: So it's put into a statute, and I have
24 to construe the statute.

25 MR. MONTGOMERY: Correct.

1 THE COURT: And the statute generally, the way the
2 Supreme Court tells me to do it is look at the plain language
3 of the statute. Okay, so that's where I'm starting from. I
4 have to construe a statute. Now, whether or not there was a
5 mutual misunderstanding or a mutual collaboration to construe
6 it differently may go to the issue of intent to defraud, but
7 why doesn't average wholesale price mean exactly that?

8 MR. MONTGOMERY: Well, because if you want to
9 approach it from a plain-meaning perspective -- and I
10 actually don't agree that that's where you go. I think this
11 is a specialized term in a specialized field, adopted by a
12 specialized agency, and that you actually treat it as a term
13 of art.

14 THE COURT: Well, did HCFA define it by
15 regulation?

16 MR. MONTGOMERY: HCFA did not define it. It
17 adopted it, your Honor. And so what it adopted was the
18 commercial term. So I am quibbling, your Honor, with the
19 path that you take. But let's leave my point aside.
20 Assuming you go through a plain-meaning exercise, I submit to
21 your Honor you're going to come back to exactly the same
22 place: What did HCFA understand?

23 THE COURT: No. No, no, no. No, no, no. What did
24 Congress understand when they put in "average wholesale
25 price"?

1 MR. MONTGOMERY: Well, that didn't happen until
2 1997. I'm back in 1991.

3 THE COURT: So you're saying, if I construe the
4 class, as has been requested, as going back to 1991 -- so
5 that's an interesting point -- I should look at what the
6 agency intended and then jump to what Congress intended?

7 MR. MONTGOMERY: Yes, exactly. Exactly. So I'm
8 starting with the agency.

9 THE COURT: All right, fair enough.

10 MR. MONTGOMERY: But let's still follow the same
11 path. So if you want to go through a plain-meaning exercise,
12 completely divorced from what we know about how this system
13 operates, I would suggest to your Honor that you actually
14 don't have a plain meaning, number one. You have average
15 price. What's average? It could be a mean proportion. It
16 could mean typical. What does wholesale price mean?

17 THE COURT: Well, "average" has a meaning.

18 MR. MONTGOMERY: It does have a meaning, but it
19 does mean two things. I don't want to press this point too
20 far, but it --

21 THE COURT: Because under any definition, you
22 wouldn't need it, right, with AWP? I mean, in other words,
23 let's say I took the most industry-favorable definition of
24 "average wholesale price," the average prices that the
25 wholesalers charge to providers. Let's just say that. And

1 let's assume I gave you every break in how you did that. It
2 still wouldn't reflect the drugs here, right?

3 MR. MONTGOMERY: Well, it certainly would reflect
4 some of the drugs here because it depends on what you think
5 about wholesaler markups. But it's a factual inquiry that
6 you would have to make. But I take your point, that as a
7 result of the operation in the real world of the system,
8 there has been a considerable erosion for many drugs, from
9 average wholesale price to actual acquisition cost, so I take
10 your point. But we're not looking at what actually happened;
11 we're just talking about what the words mean. And I don't
12 want to take up too much of your time fighting about what the
13 word "average" means, but in the dictionary, it's either
14 mathematical or it's typical. And "wholesale," that could
15 either be the manufacturer's price to the wholesaler or the
16 wholesaler's price to the retailer. It's not clear.

17 But let's assume that you reject that and you say,
18 "No, I think it is exactly clear," you're still, I submit,
19 your Honor, going to have to test that plain meaning against
20 some reality: Does it work? Does it produce an appropriate
21 result consistent with the intent of the statute? Does it
22 produce absurd results? And the meaning of AWP suggested by
23 the plaintiffs can't bear the weight they put upon it because
24 they want, first of all, manufacturers to report that price.
25 Manufacturers don't exactly know, don't have access to

1 information about average prices charged by wholesalers to
2 retailers. That's --

3 THE COURT: Why not?

4 MR. MONTGOMERY: Well, there's an information gap.
5 We don't ask them. That actually might raise some questions
6 under the antitrust laws. There are a host of questions
7 implicated by the plain meaning. Let me go through them.
8 What period of time does the average wholesale price cover?
9 What geography? What channels of trade?

10 THE COURT: Well, let's suppose I engaged in all
11 that with you. I mean, right now we have average sales
12 price, we have average manufacturing price. Let me just say
13 this: There's a way of doing it. And let's suppose I
14 engaged with you on that particular issue. That isn't what
15 you want me to do because you claim it's totally untethered
16 from the marketplace.

17 MR. MONTGOMERY: No, no, no, not at all.

18 THE COURT: You're saying that they can charge --
19 for something that the wholesaler would charge a penny for,
20 you can charge \$10.

21 MR. MONTGOMERY: If the marketplace will permit
22 that, with therapeutic competition, because, remember, for
23 many drugs that you've seen in this case -- I mean, nothing
24 is universally agreed here, but actually at the beginning of
25 a life cycle of a drug, you might actually have a

1 relationship to WAC. But, again, competition, the tether to
2 the marketplace, erodes that relationship.

3 THE COURT: Tether to the marketplace, I mean some
4 sort of reflection of acquisition cost.

5 MR. MONTGOMERY: That's right. And if for the
6 Medicare program the government had wanted a tether to actual
7 acquisition cost, it could have designed it, and it chose not
8 to.

9 THE COURT: Let me just put it this way: I
10 understand your argument with respect to the period before
11 Congress got involved.

12 MR. MONTGOMERY: Okay.

13 THE COURT: But with respect to the time period
14 once Congress got involved, the language is the plain
15 statutory meaning. Now, I understand, what does "average"
16 mean? That's what judges do every day of the week. What
17 does "wholesale" mean? What do "prices" mean? But it has
18 some bearing on acquisition cost.

19 Now, did the government collaborate somehow with
20 the industry for either good or bad reasons so that they just
21 shut a blind eye to what was happening? That may go to just
22 intent to deceive, but I'm not going to just define it as
23 having no bearing whatsoever on what the average price was
24 charged by wholesalers.

25 MR. MONTGOMERY: And I understand what you're

1 saying if you're going to pursue a plain-meaning route, but I
2 submit, your Honor, this is a term of art. It's a system.
3 And it is not -- you're treating it, your Honor, as if it is
4 intended to be a government-created regulatory regime. I
5 want to suggest it's actually the opposite. It's the
6 adoption by the government of a system which was not a
7 regulatory regime. And the government spent the better part
8 of thirteen years debating whether to impose such a regime on
9 the Medicare program. Now that they've imposed it, they're
10 still debating it.

11 THE COURT: Maybe. I've rejected the political
12 question issue. What I do as a matter of law is construe
13 statutory terms.

14 Now, I understand your point that it's a term of
15 art. If so, it hasn't been defined by Congress to be that,
16 and there are no legislative hearings that anyone's cited to
17 me to define it as a term of art. I have no basis for
18 construing it other than by what it means. And when they
19 adopted it, it cannot mean what you say it means.

20 MR. MONTGOMERY: Well, I would recommend, your
21 Honor, that you read -- and there's been some debate about
22 Mr. Scully's testimony before Congress, and the debate has
23 been about testimony in 2003 -- I suggest that you look at
24 Exhibit 63 to the Fowler affidavit, and the Exhibit 63 is
25 another bit of Scully testimony and dialogue in 2001 between

1 Mr. Scully, who's been with this since the '80s, and the
2 Congressional committee.

3 THE COURT: And what's his other statement, the one
4 that the plaintiffs are emphasizing? What exhibit number?

5 MR. MONTGOMERY: It's Exhibit B to Mr. Berman's
6 affidavit.

7 THE COURT: All right, so that's the
8 point/counterpoint you want me to look at?

9 MR. MONTGOMERY: Well, actually, I think you can
10 look at both of them.

11 THE COURT: Okay.

12 MR. MONTGOMERY: But I think what you'll find is
13 that Mr. Scully, at least the committee that he was
14 testifying before, that they understood exactly what had
15 happened. What you see --

16 THE COURT: Are there any legislative reports, any
17 conference committee reports, anything I should look at?

18 MR. MONTGOMERY: Yes. There's a 2003 House report
19 on the Medicare Modernization Act.

20 THE COURT: At the time that AWP was put in.

21 MR. MONTGOMERY: I'll have to submit something to
22 you identifying. We did cite to your Honor and I think
23 provide in the record, but I don't have the exact cite to the
24 back-and-forth in 1997.

25 Remember, in 1997, the proposal that Congress was

1 considering was to adopt an actual acquisition cost system.
2 They rejected it, and they went to 95 percent of AWP. And in
3 2000, the administration proposed creating what it called a
4 "real AWP," and Congress put a moratorium on any adjustments
5 to the AWP system. So even if you follow this plain-meaning
6 exercise for 1997, what do you do about 2000?

7 THE COURT: So you want me to just freeze 2000 out
8 of the class?

9 MR. MONTGOMERY: Well, I think you need to look at
10 2000. Congress said, "No, HCFA, you may not change the
11 external AWP system that's embodied in the statute."

12 THE COURT: Okay. All right, so let's assume for a
13 minute that you don't win that point and we move on to plain
14 language. We have a statutory scheme here where 80 percent
15 get paid off by the government and 20 percent as a copay by
16 the beneficiary. And so you've tried, as I've read the case
17 law, to paint the government as an intermediary, just the way
18 like a car dealer would be to a consumer.

19 MR. MONTGOMERY: Correct.

20 THE COURT: But, actually, the way the statute is
21 set up is a little different because the doctor bills the
22 patient.

23 MR. MONTGOMERY: Yes, but the price of admission is
24 defined by the government. In other words --

25 THE COURT: By statute.

1 MR. MONTGOMERY: By statute and by regulation.

2 THE COURT: Right, the 20 percent of AWP. It's not
3 like a --

4 MR. MONTGOMERY: Well, it's 20 percent of the
5 entire cost, which includes as a component AWP.

6 THE COURT: Fair enough.

7 MR. MONTGOMERY: And includes, of course, the
8 service or dispensing cost, so we get to the cross-subsidy
9 point and the question of whether there's a causal connection
10 to any real injury here, because even if we lose on every
11 point with your Honor on AWP, they still have to prove some
12 injury. And what was going on during this policy and
13 political discussion for the better part of thirteen years
14 was a debate whether we were going to focus on drug cost or
15 total cost. And what the Medicare Modernization Act is, it's
16 an express embodiment of a compromise that said: We're going
17 to look at the total cost. We've already got the concept in
18 the statute, and that we're going to have to address both
19 elements. And the failure to address administration costs is
20 what clearly, plainly prevented -- well, "prevent" is the
21 wrong word -- but led Congress not to adopt the acquisition
22 cost proposals that HCFA was presenting to them because they
23 didn't think that it was going to address issues of access
24 for this vulnerable population. They weren't convinced of
25 that. And until HCFA was going to step up to the plate and

1 30 percent" thing, Dr. Hartman?

2 MR. BERMAN: Well, there's two issues. Let me get
3 to Dr. Hartman. We believe that if you follow the plain
4 meaning rule that you've been talking about -- and we've
5 cited the cases -- this is not one of the exceptions for a
6 technical term or art term to be employed -- that it can only
7 have one meaning, and that is, it was supposed to be the
8 national wholesale average. And if you look at --

9 THE COURT: For what year? That's Mr. Montgomery's
10 question. Well, how do I decide what that means?

11 MR. BERMAN: Okay, you mean timewise?

12 THE COURT: Yes.

13 MR. BERMAN: If you look at -- I have a notebook
14 that I gave your Honor, and I have a chart. And what I think
15 the chart will show you is that prior to the adoption of the
16 regulation in 1997, and in the first entry, for example,
17 Congress was basing reimbursement on actual acquisition cost.

18 THE COURT: Which tab?

19 MR. BERMAN: It's called History of AWP
20 Reimbursement. I believe it's Tab 3.

21 THE COURT: Tab?

22 MR. BERMAN: Three. It should be blue.

23 THE COURT: All right.

24 MR. BERMAN: What you see in at least the first
25 four or five entries is that every time Congress defined what

1 it was trying to do, it said, "We're trying to gear our
2 payments to acquisition costs." And acquisition costs, we
3 believe, if you look at Item 2, for example, is, quote, "very
4 similar to the Average Wholesale Price." And then in Item 3,
5 "Medicare policy. . . has been to base payment for
6 'incident to' drugs on the estimated acquisition costs."
7 Then Item 4, "Estimated acquisition costs," according to HCFA
8 is, "or the national average wholesale price."

9 So if you look at Congress' intent prior to '97,
10 they were looking for estimated acquisition costs. They
11 thought that it was the same thing as average wholesale
12 price, and they eventually adopted average wholesale price.
13 So from the get-go, the reason they adopted it was, they were
14 finding it was difficult because of the lack of transparency
15 in defendants' records to find out what the real price was,
16 so they said, "Okay, we have to use the national average
17 wholesale price."

18 We have moved for summary judgment because I think
19 you hit the nail on the head when you said they aren't
20 contending, and they never have, that they meet this
21 definition. They don't. There's not one shred of
22 evidence -- and we've put in evidence to the contrary -- that
23 the reported AWP's were the national average wholesale price.
24 They weren't. That's not a contested fact.

25 THE COURT: What are you looking for summary

1 judgment on?

2 MR. BERMAN: I'm looking for summary judgment on
3 the following things: First, that each defendant either
4 directly published or caused to be published the AWP. Only
5 one defendant really contests that, that's BMS; and they
6 published the wholesale list price, which they knew would be
7 turned into AWP, and they knew the wholesale list price was a
8 phoney price. The rest of them don't contest that.

9 Second, we want your Honor to rule as a matter of
10 summary judgment that the average wholesale price is defined
11 the way we interpret it in our briefs. And I think you have
12 to do that --

13 THE COURT: Without regard to Hartman?

14 MR. BERMAN: Without regard to Hartman. I think we
15 have to do that because that's not for the jury to decide.

16 THE COURT: All right, so you want me to define it
17 as a matter of law?

18 MR. BERMAN: Yes.

19 THE COURT: All right, what's the third thing?

20 MR. BERMAN: The third thing is that there is no
21 contested issue of fact that -- and maybe I've said this,
22 your Honor -- I apologize if I'm repeating myself -- that the
23 defendants did not -- that they caused false or deceptive
24 AWP's to be published, because, again, they're not contesting
25 that --

1 THE COURT: So you want me to just basically give
2 you summary judgment? I mean, you basically want the whole
3 case to go away?

4 MR. BERMAN: Except for one thing.

5 THE COURT: What?

6 MR. BERMAN: I think there's only one issue left.

7 THE COURT: What?

8 MR. BERMAN: Damages. What is the damage? I mean,
9 obviously there's an expert dispute on --

10 THE COURT: Unfair and deceptive, is that a jury
11 call?

12 MR. BERMAN: Well, I don't think the jury gets it
13 because I think you decide that, whether it's unfair and
14 deceptive.

15 THE COURT: Under all state statutes?

16 MR. BERMAN: It's a mix on that.

17 THE COURT: Well, then I can't do it. All right,
18 so unfair and deceptive remains a jury call.

19 MR. BERMAN: But there could be a finding --

20 THE COURT: And there may be some states in which
21 it's not, but unfair and deceptive does not come to me.

22 MR. BERMAN: But there could be a finding, your
23 Honor, and I think there should be, that as a matter of
24 fact --

25 THE COURT: I will not do that on summary

1 judgment. All right, I do think it's appropriate for me, and
2 I think both sides are urging me to do that, to define AWP as
3 a matter of law. And both sides, one wants it as a term of
4 art which reflects just what the report says; one says I
5 should do it sort of based on plain language. That is for
6 me. That I will do. I'll ask you about the cost to be
7 published, whether that's disputed or not, in a second.

8 And some, like Massachusetts, that's a judge call,
9 right?

10 MR. BERMAN: That's correct.

11 THE COURT: You're saying you've looked at all the
12 remaining states that are left, and some of those are jury?

13 MR. BERMAN: I believe so, your Honor.

14 THE COURT: And you're going to at some point give
15 me that compendium.

16 MR. BERMAN: Yes. But as to Class 2, which is
17 Massachusetts only, we believe that based on the record we've
18 given you, that you can enter a summary judgment on all
19 issues but damages.

20 THE COURT: Okay, and what's the next one?

21 MR. BERMAN: That's it on summary judgment in our
22 favor, and obviously --

23 THE COURT: You've also asked essentially on
24 statute of limitations all the affirmative defenses go out,
25 right?

1 MR. BERMAN: Yes, and if you wanted us to address
2 that, Mr. Haviland will address that.

3 THE COURT: All right, so we'll get to that in a
4 minute. So can you help me out? Did you find any
5 legislative reports back in -- when was it? -- 1997 that put
6 into effect this AWP, what it means, what Congress meant?

7 MR. BERMAN: Other than these excerpts we've given
8 you, when Congress seemed to relate AWP to estimated
9 acquisition cost, the answer is "no."

10 THE COURT: All right.

11 MR. BERMAN: But to get to a couple of points that
12 Mr. Montgomery made, he said, you know, take a look at
13 Mr. Scully. I think he referenced the fact that Mr. Scully
14 testified that AWP -- and this is Point 15 in my chart -- "is
15 intended to represent the average price at which the
16 wholesalers sell drugs to their customers, which includes
17 physicians and pharmacists." And Mr. Montgomery was very
18 silent about the fact that you look to agency's
19 interpretation of its own mandate. And the office of the
20 Inspector General and CMS have both said it's supposed to be
21 average wholesale price, and the OIG has said it's supposed
22 to include all the types of discounts, rebates, free goods
23 that we claim are not reflected in the published price. So
24 not only are they not entitled to summary judgment, but we
25 believe, going back to where I was, that there's not much

1 left to try, particularly with respect to Class 2.

2 THE COURT: Have you done a compilation of the
3 statutes in which actual reliance is required?

4 MR. BERMAN: We did that for you in our class
5 certification papers.

6 THE COURT: So on those reliance statutes, do I
7 carve those out?

8 MR. BERMAN: Well, we're proceeding on the
9 theory -- remember how we unified this class -- that this was
10 an intentional fraud, and therefore we sweep in everyone.

11 THE COURT: Regardless of reliance?

12 MR. BERMAN: That's correct. And in this case --

13 THE COURT: I'm thinking that may be you're mixing
14 apples and oranges.

15 MR. BERMAN: I am mixing up apples and oranges. We
16 did not break out the reliance issue for you. You know, we
17 could do that for you at a later date, but in most states,
18 when you have an omission of fact, you get a presumption of
19 reliance. And in this state, reliance is not required.

20 THE COURT: This state, under 93A, reliance is not
21 required.

22 MR. BERMAN: That's right.

23 THE COURT: That having been said, in most fraud
24 cases, you have to prove that someone would have relied on
25 the material fact omitted, so I think we need some analysis

1 there. But, anyway, so you've given me -- I think everyone
2 agrees I need to decide AWP as a matter of law. I think I'm
3 unlikely to find that it's unfair and deceptive in cases that
4 require jury trials. Otherwise I'll hear a trial benchwise
5 if I get that far. Now, the argument --

6 MR. BERMAN: Can I go back --

7 THE COURT: Yes, is there anything else you wanted
8 to say?

9 MR. BERMAN: Yes. I want to go back to one cite,
10 and Mr. Montgomery, I think, said you should look at their
11 Exhibit 82 as the definitive exhibit. If you look at that,
12 it's a House Ways and Means report --

13 THE COURT: I don't have that down. I have 63 and
14 42, right? You have 82?

15 MR. BERMAN: An additional one is 82. It's in my
16 chart.

17 THE COURT: And what is that?

18 MR. BERMAN: It says -- this is a House Committee
19 on Ways and Means -- "AWP is intended to represent the
20 average price used by wholesalers to sell drugs to their
21 customers."

22 THE COURT: In what year?

23 MR. BERMAN: That's in 2003.

24 THE COURT: Is there any other point that you want
25 to make?